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In Re: Patent Term Extension
Application for
U.S. Patent No. 6,306,900

OPLA
OCT 11 2012
mailed

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 6,306,900, claims of which cover the human drug product Myfortic®, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 323 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of a request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 323 days.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of June 20, 2011 (76 Fed. Reg. 35899), would be 581 days. Under 35 U.S.C. § 156(c):

Period of Extension	=	RRP - PGRRP - DD - ½ (TP - PGTP)[1]
	=	1,947 - 1,089 - 0 - ½ (1,643 - 1,089)
	=	581 days (1.6 years)

Since the regulatory review period began October 31, 1998, before the patent issued (October 23, 2001), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From October 31, 1998, to and including October 23, 2001, is 1,089 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the

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[1] Consistent with 35 U.S.C. § 156(c), "RRP" is the total number of days in the regulatory review period, "PGRRP" is the number of days of the RRP which were on and before the date on which the patent issued, "DD" is the number of days of the RRP that the applicant did not act with due diligence, "TP" is the testing phase period described in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g) of 35 U.S.C. § 156, and "PGTP" is the number of days of the TP which were on and before the date on which the patent issued, wherein half days are ignored for purposes of the subtraction of ½ (TP - PGTP).

extension in the present situation, because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 581 days, would extend the patent from April 10, 2017, to November 12, 2018, which is beyond the 14-year limit (the approval date is February 27, 2004 , thus, the 14 year limit is February 27, 2018). The period of extension is thus limited to 323 days, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, April 10, 2017, to and including February 27, 2018, or 323 days.

The limitations of 35 U.S.C. 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	6,306,900
Granted:	October 23, 2001
Original Expiration Date[2]:	April 10, 2017
Applicant:	Barbara Haeberlin, et al.
Owner of Record:	Novartis AG
Title:	Enteric Coated Pharmaceutical Compositions
Product Trade Name:	MYFORTIC® (mycophenolic acid)
Term Extended:	323 days
Expiration Date of Extension:	February 27, 2018

[2]Subject to the provisions of 35 U.S.C. § 41(b).

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.

Mary C. Till
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: MYFORTIC®
(mycophelolic acid)
Docket No.: FDA-2004-E-0267